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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,288	11/13/2001	Frans Gerrit Davelaar	AHP-98249	5326

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,288	DAVELAAR, FRANS GERRIT	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/28/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1-9 and 15-22 are objected to because of the following informalities: Independent claim 1 recites "SHS" and claims 1 and 15 recite, "TRT". Claim 22 recites the abbreviation, "TRTV". These claims should recite the full name, followed by the acronym to avoid any confusion. This objection also affects claims 2-9 and 16-21. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 13, 14 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of protecting an avian host from "TRT and/or TRT". While it is clear from the disclosure that "TRT" is turkey rhinotracheitis, see page 1, line 10, it is unclear if there is any difference between the TRTs recited in the claim. This rejection also affects claims 2-9.

Claim 13 recites the limitation "vaccine" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is presumed that the claim is intended to depend from claim 12. In the interest of compact prosecution, claim 13 will be treated as if it depends from claim 12. However, this treatment does not relieve applicant of the burden of responding to this rejection. This rejection also affects claim 14.

Claim 18 recites the limitation "said post-*in ovo*" in 1. There is insufficient antecedent basis for this limitation in the claim. This claim is presumed to be intended to depend from claim 17 and will be treated as such in the interest of compact prosecution. However, this treatment does not relieve applicant of the burden of responding to this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10 and 11 are drawn to a method of protecting turkeys and chickens from exposure to virulent strains of turkey rhinotracheitis virus. Claims 12-14 are drawn to an *in ovo* vaccine for protecting turkeys and chickens from exposure to virulent turkey rhinotracheitis virus. The nature of the invention is drawn to protecting poultry against rhinotracheitis virus disease. There is no working example demonstrating that administration of the live, attenuated TRT shields poultry from exposure to virulent strains. The working examples only demonstrate protective efficacy against virulent strains upon challenge, see Table 7 for example. The vaccine art does not teach or suggest a method of inhibiting exposure to a virus, only protection against virulent strains upon administration of an appropriate vaccine. Therefore, although one skilled in the art has the ability to protect against virulent virus strains with an appropriate vaccine, it is beyond the skill of those in the art to prohibit the exposure to virulent strains. For these reasons,

it is determined that an undue quantity of experimentation would be required of the skilled artisan to make and/or use the invention.

Claims 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims require that a method of inoculating poultry with at least about $10^{3.2}$ $TCID_{50}$ to about $10^{4.2}$ $TCID_{50}$ per egg of a live, attenuated strain of TRT *in ovo* results in substantially no decrease, less than about 5% decrease, or less than about 1% decrease in the percentage of eggs that hatch. On page 5, the working example indicates that administering $10^{5.5}$ $TCID_{50}$ (this dosage is only a presumption since the disclosure recites "105.5 $TCID_{50}$" in line 10) *in ovo* increases the percent hatchability by 1% compared to un-vaccinated controls, see Table 1. However, in example 2 starting on page 9, the disclosure demonstrates that *in ovo* vaccination with $10^{4.2}$ $TCID_{50}$ results in a decrease in hatchability of 6.7%, see Table 6. This data provided in the disclosure indicates that a larger dose of attenuated TRT results in a higher percentage of hatchability while lesser dose of the vaccine inoculant comprising a range recited in the claims, results in a decrease in hatchability. The skilled artisan would be unable to obtain a higher percent of hatchability with the recited dose ranges because the specification does not provide guidance for improving the results obtained in the working examples. Therefore, it is determined that the invention would require an undue quantity of experimentation for one skilled in the art to make and/or use the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-9, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Poston et al. (WO 99/53950, provided in the IDS).

Claims 1-9 are drawn to a method of protecting an avian host against TRT by administering *in ovo* a composition, on or before day 24 of incubation, comprising a live, attenuated TRT virus of about $10^{3.2}$ $TCID_{50}$ to about $10^{4.2}$ $TCID_{50}$. Claim 15 is drawn to a method of inoculating poultry against TRT by administering the same dose range. Claims 17 and 18 state that infectious bronchitis vaccine and Marek's disease vaccine are administered at approximately 1 day of age post-*in ovo*.

Poston et al. anticipate a method of protecting an avian subject against TRT by administering *in ovo* a composition comprising a live vaccine virus, which includes TRT and interferon to an avian subject, such as turkeys or chickens in the last quarter of *in ovo* incubation. The virus dose range of Poston et al. is administered from about 10^{-2} EID_{50} to about 10^{6} EID_{50}, see claims 1, 6-11, 13-15, 18, 22, 24, 26-28, 31, 32, 36 and 38. The live vaccine of Poston et al. include any commercial live virus vaccines for use in post-hatch avians, see page 11, lines 10-13 for example. The last quarter of *in ovo* incubation is embryonic day 18 for a chicken and between the embryonic day 21 and 27 for a turkey, see page 14, lines 20-28. Poston et al. also

anticipate administering Marek's disease virus or infectious bronchitis virus post-*in ovo* during the first three days post-hatch, see claims 39, 43 and 46.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Poston et al., *supra*.

Claim 16 further requires co-administering another vaccine selected from Newcastle Disease or infectious bursal disease.

See the previous citations of Poston et al. above. Claim 17 of Poston et al. is drawn to administering Newcastle disease virus *in ovo* for protective purposes. Poston et al. teach administering two or more vaccine formulations, see page 16, lines 30-33. Although the reference does not explicitly teach administering TRT and NDV together *in ovo*, Poston et al. specifically teach administering more than one viral vaccine for better efficiency and cost effectiveness. Since Poston et al. separately teach *in ovo* administration of TRT and NDV and infectious bursal disease virus and specifically teach administering more than one vaccine composition, the reference anticipates or would have rendered instant claim 16 prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poston et al. as applied to claims 1, 3-9, 15, 17 and 18 above, and further in view of Ricks et al. (Advances in Veterinary Medicine. 1999; 41: 495-515, provided in the IDS).

Claim 2 is states that the amount administered is in a suitable vehicle of approximately 0.05 to 0.1 ml per egg. Claim 22 is drawn to a method of providing elevated titers to TRTV by administering *in ovo* an attenuated TRTV antigen in the range of about $10^{3.2}$ $TCID_{50}$ to about $10^{4.5}$ $TCID_{50}$ in a suitable vehicle of approximately 0.05 to 0.1 ml per egg.

See the teachings of Poston et al. above. Poston et al. do not teach the volume administered.

However, Ricks et al. teach that automated egg injection equipment conventionally administers 0.05 to .2 ml per egg, see the third paragraph on page 497.

One of ordinary skill in the art at the time the invention was made would have been motivated to administer the conventional volume of to eggs, taught by Ricks et al. in the method of Poston et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for administering the conventional volume in an automated egg injection system in the method of Poston et al. because Poston et al. also use a high-speed automated egg injection system, see page 16, lines 11-20. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley